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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,472	03/26/2001	Wilson Smart	Kum11Sil.Prb	6422

7590 04/19/2004  
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EXAMINER  
NASSER, ROBERT L

ART UNIT	PAPER NUMBER
3736	19

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/816,472

Applicant(s)

SMART ET AL.

Examiner

Robert L. Nasser

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31,34,36-53 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) 28-30 and 38-47 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48 and 49 is/are allowed.
- 6) ☒ Claim(s) 1-10,12-27,31,34,36,37,50-53 and 55-59 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Claims 28-30 and 38-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10, 12, 27, 31, 37, 51-53, 55, 56, 57, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al 5,591,139. Lin et al shows a device including a single crystal silicon substrate 46 having a x (length) y (width) and z dimension, where the top and bottom surfaces extend in the x and y dimension, where the substrate has a body portion 12 at a body end and a penetration end 18, and a biosensor 104 integrated into the substrate (see figure 6). With respect to claims 2-4, the penetration ~~portion~~ end tapers from the body to a tip at the penetration end, where the taper is uniform in the X direction. With respect to claims 5-8, the substrate has a length in the x directions of 2.5-7.5 mm (see figure 2A and the accompanying discussion), where the penetration depth is 1-6 mm. In addition, the y dimension depth

at the penetration depth is 80 micrometers, which is "about" 30 and the Y dimension width at the body end is 140 micrometers, which is "about" 200 micrometers. Claim 10 is rejected in that the point is a symmetrically shaped point. Claim 12 is rejected in that there is structure in figure 6 for interfacing with an analyte meter and there is a signal carrier between the sensor and the interface. Claim 27 is rejected in that the sensor is "near" the penetration end.

Claim 31 is rejected in that the biosensor is on a planar surface of the substrate. Claim 37 is rejected in that the substrate is single crystal silicon. Claims 51-53, 55, and 56 are rejected for the reasons given above. Claim 57 is rejected in that at tip portion 86, the thickness is less than the thickness of the body portion. Claim 58 is rejected in that layer 46 is single crystal silicon.

Claims 1-8, 10, 12, 25-27, 31, 32, 34, 36-37, 50-53, and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Frazier et al WO 01/93930. Frazier et al has a silicon substrate (see page 8, line 10) and has a body portion 18 and a penetration portion 11, with a biosensor 17 mounted on the penetration portion. With respect to claims 2-4, the penetration portion end tapers from the body to a tip at the penetration end, where the taper is uniform in the X direction. With respect to claims 5-8, the substrate has the recited dimensions (see columns 9 and 10). Claim 10 is rejected in that the point is a symmetrically shaped point. Claim 12 is rejected in that there is structure discussed in column 7, lines 21-26 for interfacing with an analyte meter and there is a signal carrier between the sensor and the interface. Claim 5 is rejected in that the sensor is optical. Claim 26 is rejected in that the sensor is spaced enough from the

body portion to penetrate into the body. Claim 27 is rejected in that the sensor is near the penetration end. Claim 31 is rejected in that the biosensor is on a planar surface of the substrate. Claims 34 and 36 are rejected in that there are multiple biosensors and different x dimension depths. Claim 37 is rejected in that the substrate is single crystal silicon. Claim 50 is rejected in the, in addition to the reasons given above, there are multiple biosensors sensing multiple parameters. Claims 51-53, and 57 rejected for the reasons given above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 13-15, 18, and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of Say et al. With respect to claim 9, Say et al shows a chisel shaped microneedle. Therefore, it would have been obvious to modify Lin et al to use the needle shape taught by Say et al, as it is merely the substitution of one known equivalent needle shape for another. With respect to claim 13, Lin et al does not teach how the device is attached to the external device. Say et al shows a similar analyte monitoring device where the microneedle device is attached to the external device with contact pads 49. Hence, it would have been obvious to modify Lin et al to use such an attachment technique, as it is merely the selection of a well known attachment technique in the art. With respect to claims 14 and 15, Lin et al teaches an ion chip analyzer, 104, but does not state what kind of analyzer it is. Say et al uses a

electrochemical analyzer. Hence, it would have been obvious to modify Line et al to use an electrochemical analyzer, as it is merely the substitution of one known equivalent analyzer for another. Claim 18 is rejected in that there is an electrically insulating silicon dioxide layer 54 on the substrate. Claim 20 is rejected in that all the electronic components are deposited on the SiO<sub>2</sub> layer (see column 8, lines 1-14). Therefore, it would seem clear that the biosensor 104 would also be on the SiO<sub>2</sub> layer. Claims 21-24 are rejected in that the examiner takes official notice that the techniques recited are well known techniques used to deposit contacts on a substrate and therefore it would have been obvious to modify the above combination et al to use the recited techniques.

Claims 9 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Say et al. With respect to claim 9, Say et al shows a chisel shaped microneedle. Therefore, it would have been obvious to modify Frazier et al to use the needle shape taught by Say et al, as it is merely the substitution of one known equivalent needle shape for another. With respect to claim 13, Frazier does not teach how the device is attached to the external device. Say et al shows a similar analyte monitoring device where the microneedle device is attached to the external device with contact pads 49. Hence, it would have been obvious to modify Lin et al to use such an attachment technique, as it is merely the selection of a well known attachment technique in the art. With respect to claims 14 and 15, Frazier uses an electrochemical sensor to measure analyte levels.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of Say et al, as applied to claims 9, 13-15, 18, and 20-24, further in

view of in view of Meade et al. Meade teaches that electrogravimetric sensors and electrochemical sensors are equivalent for analyte monitoring. Hence, it would have been obvious to modify the above combination to use an electrogravimetric sensor, as it is merely the substitution of one known equivalent for another.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Say et al, as applied to claims 9 and 13-15, further in view of in view of Meade et al. Meade teaches that electrogravimetric sensors and electrochemical sensors are equivalent for analyte monitoring. Hence, it would have been obvious to modify the above combination to use an electrogravimetric sensor, as it is merely the substitution of one known equivalent for another.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of Say et al, as applied to claims 9, 13-15, 18, and 20-24, further in view of in view of Kim et al. Kim et al shows a silicon oxide insulative layer on the substrate. It would have been obvious to modify the above combination to use the silicon oxide layer in place of the silicon dioxide layer, as it is merely the substitution of one well known insulative layer for another.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of Smart 5,801,057. Smart teaches the use of an optical sensor to measure analyte levels. Hence, it would have been obvious to modify the above combination to use an optical sensor, as it is merely the substitution of one known equivalent for another.

Claims 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of Kim et al. With respect to claims 34 and 36, Lin et al only has a single analyte sensor. Kim et al shows multiple sensors for measuring glucose to increase accuracy of measurement. Hence, it would have been obvious to modify Lin et al to include multiple sensor, to increase the accuracy.

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of the Smart et al article entitled "The use of Silicon Microfabrication Technology in Painless Blood Glucose Monitoring." Smart et al further teaches that a needle with a constant taper is preferred, as it reduces stresses on the needle. Hence, it would have been obvious to modify Lin et al to use such a needle, in order to reduce stresses on the needle during use. The examiner notes that the reference qualifies under 103(a) and therefore is available as in an obviousness combination.

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of the Smart et al article entitled "The use of Silicon Microfabrication Technology in Painless Blood Glucose Monitoring." Smart et al further teaches that a needle with a constant taper is preferred, as it reduces stresses on the needle. Hence, it would have been obvious to modify Frazier et al to use such a needle, in order to reduce stresses on the needle during use. The examiner notes that the reference qualifies under 103(a) and therefore is available as in an obviousness combination.

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 11 defines over the art in that none of the



art teaches the microfillet portion. In view of the discussion on page 12 of the specification, it is clear that the inclusion of such a portion is more than merely a change in shape and therefore defines over the art of record.

Applicant's arguments filed 1/26/2004 have been fully considered but they are not deemed to be persuasive.

Applicant has asserted that Lin et al does not have a silicon substrate because it is a complicated needle with many layers. However, one of the layers, layer 46, is a single crystal silicon layer which is a substrate. The claims do not state that the device is made entirely from a single crystal silicon substrate, just that it has such a substrate. Hence, it is the examiner's position that Lin et al meets the claim language and the rejection is being maintained.

Applicant has further asserted that the device of Frazier is not made from a silicon substrate as it is separated from the substrate after formation. However, the examiner directs applicant's attention to column 8, the second paragraph, where it clearly states that the microneedle may be made from silicon.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

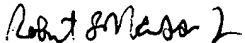
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Robert L. Nasser  
Primary Examiner  
Art Unit 3736

RLN  
4/16/2004

ROBERT L. NASSER  
PRIMARY EXAMINER